

Notice of Allowability

Application No.

09/589,476

Examiner

Frederick F. Krass

Applicant(s)

CARSON ET AL.

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment dated March 28, 2006.
2. ☒ The allowed claim(s) is/are 1,3,4,11,13,14,26-29,34 and 35.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
- ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Interview Summary (PTO-413), Paper No./Mail Date 04/05/06.
- ☒ Examiner's Amendment/Comment
- ☒ Examiner's Statement of Reasons for Allowance
- ☐ Other _____

Frederick F. Krass
Primary Examiner
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Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Monique Perdok Shonka on 04/05/06.

The following changes have been made:

- 1) In the title, "cancer" has been replaced with --- multiple myeloma ---
- 2) Page 1 of the specification, second line, "pending" has been replaced with --- , now USP 6,545,034 ---
- 3) Claim 1, first line, "to treat" has been deleted and replaced with --- of treating --
- 4) Claim 1, second line, "mammalian cancer" has been replaced with --- multiple myeloma ---

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5) Claim 1, second line, immediately after "cells" there has been inserted --- in said mammal ---

6) Claim 1, third-to-last line, "cancerous bone marrow" has been deleted and replaced with --- multiple myeloma ---

7) Claim 1, penultimate line, immediately before "plasma" there has been inserted --- blood ---

8) Claim 1, penultimate line, "level" has been changed to --- concentration ---

9) Claim 1, penultimate line, "about" has been deleted.

10) Claim 1, penultimate line, and claim 26, third line, in each instance "250" has been changed to --- 200 ---, and "800" has been changed to --- 750 ---, respectively.

11) Claim 4, second line, immediately after "administered" there has been inserted --- orally or by injection ---

12) Claim 4, second line, "cancer" has been deleted.

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13) Claim 26, third line, immediately before "plasma" there has been inserted ---
blood ---

14) Claim 26, third line, "level" has been changed to --- concentration ---

15) Claim 26, third line, "compound" has been changed to --- etodolac ---

16) Claim 26, third line, both occurrences of "about" have been deleted.

17) Claim 26, penultimate line, "cancerous" has been deleted.

18) Claim 29, first line, immediately before "plasma" there has been inserted ---
blood ---

19) Claim 29, first line, "about" has been deleted.

Examiner's Comment Re: Drawings

In the originally filed drawings (06/07/00), there was a single Figure 8, with four unlabeled graphs on the page. In the amendment to the specification dated 06/10/04, the description of the drawings was changed to refer to Figures "8A", "8B", "8C" and

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"8D". No corresponding amended drawings were concurrently submitted therewith, however.

Accordingly, the drawings filed 06/07/00 are objected to insofar as the graphs in Figure 8 are not separately labeled so as to correspond to the description in the specification. Corrected drawings are required.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

None of the prior art fairly suggests, teaches or discloses treating multiple myeloma with an etodolac compound at plasma levels of 200 uM to 800 uM.¹ As discussed in Applicant's specification and response(s), when an etodolac compound is used at these levels it unexpectedly kills cancer cells, rather than merely inhibiting their growth.

The Yasui et al article in the journal "Blood" is cited as demonstrating the state of the art.²

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

¹ See the figures submitted with the application as originally filed. The levels shown there are far higher than any specified by the prior art. See, e.g., the third full paragraph on p. 6 of the instant specification (disclosing a level of 33 uM).

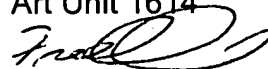
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
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² The reference also provides independent post-filing verification of Applicant's results.